

1 IN THE UNITED STATES DISTRICT COURT

2 IN AND FOR THE DISTRICT OF DELAWARE

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4 EDWARDS LIFESCIENCES AG and : Civil Action

5 EDWARDS LIFESCIENCES LLC, :

6 :

7 Plaintiffs, :

8 :

9 v. :

10 :

11 COREVALVE, INC., :

12 and MEDTRONIC COREVALVE, LLC, :

13 :

14 Defendants. : No. 08-91 (GMS)

15 - - -

16 Wilmington, Delaware

17 Wednesday, January 12, 2011

18 12:15 p.m.

19 Telephone Conference

20 - - -

21 BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge

22 APPEARANCES:

23 JACK B. BLUMENFELD, ESQ.

24 Morris, Nichols, Arsht & Tunnell LLP

25 -and-

JOHN E. NATHAN, ESQ., and

CATHERINE NYARADY, ESQ.

Paul, Weiss, Rifkind, Wharton & Garrison LLP
(New York, N.Y.)

Counsel for Plaintiffs

1 APPEARANCES CONTINUED:

2 JOHN W. SHAW, ESQ., and
3 PILAR GABRIELLE KRAMAN, ESQ.
4 Young Conaway Stargatt & Taylor LLP
5 -and-
6 BRIAN FERRALL, ESQ.
7 Kecker & Van Nest LLP
8 (San Francisco, CA)

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10 Counsel for Defendants

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12 THE COURT: Good morning. Counsel, who is on
13 the line for Edwards Lifesciences?

14 MR. BLUMENFELD: Good afternoon, Your Honor.
15 Jack Blumenfeld along with John Nathan and Catherine Nyarady
16 at Paul Weiss.

17 THE COURT: Good morning.

18 And for Corevalve?

19 MS. KRAMAN: Good afternoon, Your Honor. This
20 is Pilar Kraman from Young Conaway. With me on the line is
21 John Shaw, and from Kecker & Van Nest Brian Ferrall.

22 THE COURT: Do we have everyone now?

23 MR. BLUMENFELD: I think that's everyone, Judge.

24 THE COURT: Mr. Blumenfeld, are you going to
25 handle this?

MR. BLUMENFELD: I am going to try, Your Honor.

The reason we asked for this conference --

1 THE COURT: You usually do okay, Mr. Blumenfeld.

2 MR. BLUMENFELD: Thank you, Your Honor.

3 We are seeking a determination that Mr. Nathan
4 and his team at Paul Weiss and Dr. Buller, you may remember
5 from trial, can participate in two reexaminations that were
6 started by Medtronic, which is Corevalve's parent.

7 To give you a little bit of background, I don't
8 think I need to remind you that we had a trial last spring
9 and we are at the posttrial motions stage.

10 At the trial Corevalve didn't assert any prior
11 art defenses. They dropped them the night before trial
12 started. But after trial, Medtronic then filed
13 reexamination requests on both the '552 and the '462
14 patents. And Medtronic in those requests cited certain
15 prior art, and they made arguments based essentially on
16 three things: first, Your Honor's claim construction on the
17 two patents; second, Mr. Nathan's closing argument about the
18 Corevalve device, which we don't agree with, we think was
19 out of context, but that's what they did; and third, Dr.
20 Buller's testimony about the Corevalve device and certain
21 photographs that he had used at trial.

22 And Medtronic submitted parts of the litigation
23 record to the Patent Office, and a member of their trial
24 team even submitted a declaration, attaching certain
25 demonstrative exhibits that we had provided to them before

1 and during the trial. Medtronic provided parts of the trial
2 transcript, including some of Dr. Buller's testimony, to the
3 Patent Office.

4 The situation we are in now is that the Patent
5 Office has rejected Claim 1 of the '552 patent based on the
6 Irsek prior art and has rejected Claim 1 of the '462 patent
7 based on the Strecker prior art. Of course, there was no
8 trial record on either Irsek or Strecker because they were
9 dropped.

10 But Mr. Nathan and his colleagues at Paul Weiss
11 spent a couple years studying those patents and taking
12 discovery about them. There is, of course, also nothing
13 confidential about those two patents.

14 Now, Mr. Nathan and Paul Weiss don't do any
15 patent prosecution work for Edwards. But given the record
16 that Medtronic made in the Patent Office about what Mr.
17 Nathan argued and what Dr. Buller said, Edwards has
18 concluded that it's necessary to have them involved in the
19 reexamination. And certainly from our point of view, there
20 is nobody in a better position to respond to allegations
21 about either the prior art or what Mr. Nathan and Dr. Buller
22 said at trial than Mr. Nathan and his team and Dr. Buller.

23 So we approached Corevalve's lawyers. They
24 won't agree that Mr. Nathan or Dr. Buller can participate in
25 the reexams.

1 Just to put the issue in context, under the
2 protective order, Paragraphs 4 and 6, attorneys working on
3 patent prosecution can't have access to confidential
4 information of the other party. And here, you know, Mr.
5 Nathan and Dr. Buller certainly did have access to
6 confidential information from Corevalve.

7 I am not sure exactly why Corevalve's lawyers
8 can participate, their trial lawyers, who had access, can
9 participate but they don't believe Edwards can. But that's
10 their position. We don't agree with it. But we certainly
11 don't want to run into a situation where there is a
12 suggestion we are violating a Court order. And the
13 protective order also permits any party to ask the Court to
14 modify the protective order that's in Paragraph 29.

15 I don't know the extent to which Your Honor has
16 been involved in these prosecution bar issues. In my
17 experience, in some circumstances, it makes sense. We don't
18 see how it really makes sense here, for a couple of reasons.

19 First, because Medtronic opened up this whole
20 issue. And they shouldn't, in our view, be able to have
21 their litigation lawyers say, you know, look at what Mr.
22 Nathan and Dr. Buller said and then say, but Mr. Nathan and
23 Dr. Buller can't respond. It shouldn't be one direction.

24 The second reason is because the arguments about
25 Irsek and Strecker are all based on things in the public

1 record, either the prior art itself, the trial record about
2 the Corevalve device, none of that is confidential. And for
3 that reason, and I think this is supported by case law, we
4 don't think the reexamination should be subject to the
5 prosecution bar. There is no good reason why, with
6 Corevalve or its parent having opened up the statements by
7 Mr. Nathan and Dr. Buller in the Patent Office, they
8 shouldn't be able to respond.

9 We don't know of any good reason why Mr. Nathan
10 and his team shouldn't be able to address Irsek and
11 Strecker, which are not confidential information, which they
12 have been studying for years, and to deal with that during
13 the reexamination.

14 That's the way we see it.

15 And the relief we ask for is a determination
16 that Mr. Nathan and his team and Dr. Buller can participate
17 in those reexaminations.

18 THE COURT: Okay. Thank you, Mr. Blumenfeld.

19 Who is going to respond?

20 MR. FERRALL: I will, Your Honor. This is Brian
21 Ferrall. Good afternoon.

22 First, let me make one thing very clear, that I
23 have told counsel for Edwards from the beginning that if
24 what they are interested in doing is the same as what an
25 associate at my firm was asked to do, that we have no

1 problem with that.

2 To the extent this is a sort of sauce for the
3 goose, sauce for the gander argument, then it's not
4 something that we should be bothering the Court with.

5 Let me explain how it was that an associate,
6 Michael Gatterberg, in my firm, submitted an affidavit.

7 Medtronic did not rely on trial counsel, either
8 my firm or the Knobbe Martens firm, for reexam. We did not
9 play a role formulating the reexam or submitting that. We
10 are not reexam counsel.

11 Medtronic hired separate counsel for that, just
12 like we are suggesting Edwards should do.

13 Rather, what happened was, in response to the
14 original reexam submission, which included some trial
15 evidence, the Patent Office asked that the documents be
16 authenticated. On that basis, and on that basis alone, we
17 submitted a, essentially a ministerial affidavit,
18 authenticating documents from the trial and demonstratives
19 that had been exchanged. All public information and purely
20 administrative.

21 And, so, again, if what Edwards needs to do is
22 to counter that evidence with authenticating
23 counter-designations of trial testimony or counter-evidence,
24 we have no problem with that.

25 What I am hearing and what I understand Edwards

1 would like is a wholesale exemption from the prosecution
2 bar. And I think the case law, the Deutsche Bank Federal
3 Circuit case that came out last year, makes a couple of
4 things pretty clear. It draws a clear distinction between
5 purely administrative roles which the Federal Circuit
6 observed typically almost never involve competitive
7 decision-making, which is the touchstone of these issues,
8 versus active involvement in prosecution, including the
9 right to formulate and make arguments or formulate new
10 claims or amend claims.

11 As I understand it, Edwards wants the latter,
12 not the former.

13 So the second thing that the Deutsche Bank case
14 makes clear is that when a patent holder such as Edwards is
15 seeking an exemption from a prosecution bar, it is their
16 burden to show both a low risk of inadvertent use of
17 confidential information and that the burden tips in their
18 favor.

19 I have not really heard either from Edwards,
20 either in the meet-and-confer or today, what -- there has
21 been, I think, no recognition that, the parties to this
22 case, as Your Honor I am sure will remember, have had a
23 number of disputes in the course of the litigation about the
24 sensitivity of materials. Edwards has had their share of
25 times when they have prevented the disclosure of

1 confidential information and the like.

2 Indeed, I looked through the record back before
3 my firm was involved. In June of 2009, I believe it was,
4 there was a discovery conference in which Edwards asked the
5 Court for an exception to the protective order to allow it
6 to use evidence about this Irsek prior art, confidential
7 evidence, that is, because there was some confidential
8 testing of the Irsek device. And Edwards wanted to use that
9 in parallel litigation in Europe. And they also wanted to
10 use confidential documents that Corevalve had characterizing
11 its own device in Europe.

12 The Court denied that motion, and rightfully so,
13 needless to say, is our view about it.

14 So the idea that arguments about Irsek or
15 confidential documents about the characterization of the
16 product will not be at risk of disclosure if Paul Weiss has
17 cart blanche in the reexam I don't think is a fair
18 characterization of the history of the case.

19 There is one other thing I want to point out. I
20 proceed with some trepidation, because, of course, if I
21 don't prevail today, I don't want to give Edwards a roadmap
22 about what to do.

23 But there are, also, documents describing future
24 Corevalve products that have been exchanged in the case.
25 They have been the subject of deposition. They have been

1 deposition exhibits. So that is sort of the prototypical
2 type of risk that a prosecution bar seeks to prevent, to
3 make sure that in the course of prosecution, which, and it
4 can happen in reexam, also, of course, that claims are not
5 amended with the idea of reaching a future product while
6 overcoming the prior art.

7 So, you know, the risk that the Deutsche Banc
8 case talks about of inadvertent use of the inability of the
9 human mind to compartmentalize what one knows when acting on
10 behalf of a client, I think, is directly applicable here.

11 So we have always operated under the belief that
12 trial counsel were not going to be actively working on
13 participating in reexam. And the prospect of Paul Weiss
14 participating in claim amendments or Dr. Buller submitting a
15 declaration, talking about why he said certain things at
16 trial in light of confidential documents or, worse yet, I
17 guess, Dr. Buller participating in a confidential interview
18 with the examiner where there is not even any record of what
19 is said, I think goes right to the heart of what the
20 prosecution bar in the protective order was designed to
21 prohibit.

22 THE COURT: Thank you, Mr. Ferrall.

23 Mr. Blumenfeld.

24 MR. BLUMENFELD: Your Honor, Thank you.

25 First of all, you know, Edwards does have other

1 reexamination counsel. The idea was not that Paul Weiss
2 would be handling it alone.

3 THE COURT: Let me get you to respond, and say
4 whatever you want to say, though, to Mr. Ferrall's point
5 that the affidavit at issue, prepared and submitted by, I
6 gather, an associate who was involved in the litigation, was
7 very limited.

8 MR. BLUMENFELD: The declaration attached
9 documents and it was fairly limited. What was not limited
10 was the arguments that Medtronic's counsel made about what
11 Mr. Nathan argued and what Dr. Buller testified.

12 So we don't think it's enough for us to be able
13 to authenticate our own documents. That's not what we are
14 talking about here.

15 But when someone comes in and says, here's how
16 the reexamination ought to come out and we are talking about
17 the validity, patentability of these patents, because Mr.
18 Nathan argued this to the jury in his closing, we feel that
19 Mr. Nathan has to be able to participate in responding to
20 that. The same with Dr. Buller's testimony.

21 So it is a little different. What we are
22 talking about here, though, isn't confidential Corevalve
23 information, which I understand that Mr. Ferrall is
24 concerned about.

25 First, there is nothing confidential about Irsek

1 or Strecker. And there is nothing confidential about the
2 current Corevalve device. It's out there. We have it. It
3 was discussed at length at trial. But essentially, what we
4 are talking about here is responding to office actions about
5 prior art. We are not asking for this leave in order for
6 Mr. Nathan or Dr. Buller to be able to be involved in claim
7 amendment strategy, but to respond about prior art. And
8 that part, I think, there really is no concern about
9 confidential information.

10 And the case law, there are decisions in the
11 last year from both Judge Robinson and Judge Thyng about
12 how prosecution bars really shouldn't apply in
13 reexaminations because they are different in that you can't
14 broaden the claims. We are not talking about that.

15 What we are talking about is responding to
16 arguments that were made about Irsek and Strecker and to
17 some extent about the Corevalve device at trial.

18 We just don't see that there is -- one, we think
19 it's necessary; and, two, in that context, we don't see a
20 risk of inadvertent disclosure.

21 THE COURT: Mr. Ferrall, could you respond to
22 that narrow point?

23 MR. FERRALL: Yes. First of all, as Mr.
24 Blumenfeld has said from the outset, Irsek and Strecker were
25 not the subject of the trial. So this is not about

1 characterization or recharacterizing Mr. Nathan's arguments
2 about those pieces of prior art, to my knowledge.

3 What it is about is what was said and presented
4 to the jury, and the basis for the jury verdict about the
5 Corevalve device. And as I see it, we didn't submit
6 argument about what Mr. Nathan meant or what Dr. Buller
7 meant but may not have said at trial. We presented what was
8 said, "we" meaning our reexam counsel. I didn't do
9 anything. But we presented what was said, and argued from
10 that.

11 And, of course, Edwards can do the same. They
12 can talk about the trial record and argue from that.

13 What was in Mr. Nathan's mind or Dr. Buller's
14 mind about the Corevalve device when they said something at
15 trial is irrelevant. That's not what the reexam is based
16 on. That's where the danger comes, is that Mr. Nathan or
17 Dr. Buller gets in front of the examiner and says, well,
18 what I really meant was that the Corevalve device has these
19 properties and this is why, you know, this is why it behaves
20 this way or this is why it meets that limitation. And that
21 is where the risk of inadvertent use is very high.

22 Plus, it's not really pertinent to what the jury
23 decided, of course, or what was presented in reexam, which
24 is, of course, all the public record, not what was in their
25 head.

1 THE COURT: Okay. Mr. Blumenfeld, your reaction
2 to that.

3 MR. BLUMENFELD: Yes. A couple things.

4 One, as Mr. Ferrall said, what they pointed out
5 was what Mr. Nathan and Dr. Buller said to the jury about
6 the Corevalve device. But as he also said, they did more
7 than that. They argued from that. And what they argued,
8 among other things, was what the import of Mr. Nathan's
9 statements was --

10 THE COURT: When you say "they," you are
11 referring to?

12 MR. BLUMENFELD: Medtronic. Medtronic or
13 Corevalve.

14 THE COURT: In the reexam.

15 MR. BLUMENFELD: In the reexam. What they
16 argued about was, well, based on what Mr. Nathan said and
17 based on what Dr. Buller testified, this is how the reexam
18 should come out. I don't think there is any question about
19 that. When they are going to make arguments like that, we
20 don't see how we can respond to them without the people who
21 in a sense are being accused of having made those statements
22 being able to respond to them in whatever way Edwards thinks
23 is appropriate.

24 Edwards has invested a huge amount in Mr. Nathan
25 and his team. And for them not to be able now to talk about

1 Irsek and Strecker, even though they weren't at trial, they
2 were always part of this litigation. And not to be able to
3 talk about an issue that Medtronic has opened up in the
4 Patent Office by saying, the import of what Mr. Nathan and
5 Dr. Buller have said is this, it seems to us is very unfair.
6 And it really doesn't seem to me that, when you are talking
7 about prior art and patentability, that there is any real
8 danger about inadvertent disclosure of information. It's
9 just different information.

10 We think we do have to be able to defend against
11 what they have done in the Patent Office. There is nobody
12 better to do that than the people who are accused and who
13 have spent years living with this and studying the prior
14 art.

15 THE COURT: If the danger, Mr. Ferrall, of
16 inadvertent use is not real, why isn't Mr. Blumenfeld
17 correct in his last assertion?

18 MR. FERRALL: Well, Your Honor, I believe the
19 danger of inadvertent use is real, because, if it were not
20 the case, I wouldn't have this position, that's for sure.
21 My client wouldn't ask me to oppose this. I believe the
22 danger of inadvertent use is real because the discussions
23 and the argument, I think, that Mr. Nathan or Dr. Buller may
24 make will be informed by what they had in their mind
25 regarding confidential Corevalve material. The idea that

1 the Corevalve product is publicly known is true, yes. But
2 not all of the attributes of it are publicly known. Indeed,
3 at trial, Your Honor, you may recall, among other things,
4 Dr. Buller sitting on the stand saying I have next to me a
5 box of confidential Corevalve documents that I only had
6 access to as a result of this litigation, and they all
7 characterize the Corevalve documents as being a cylinder, or
8 something to that effect.

9 Now, that was just one example that came up at
10 trial. But the point is, there is no doubt that both Dr.
11 Buller and Mr. Nathan have in mind detailed attributes of
12 the Corevalve product that are not public.

13 And how are we to know, when they formulate
14 their arguments to the Patent Office that say, well, what I
15 meant, really, was this, that and the other, that they are
16 not using their confidential information in doing so?

17 When we prepared the reexam, Medtronic did not
18 come to us and say, you know, we really want you to think
19 deeply about all that you have in your mind about Corevalve
20 or Edwards and the like in order to formulate these
21 arguments to the Patent Office.

22 Our reexam counsel -- and that's not
23 withstanding all of the millions of dollars that Corevalve
24 and Medtronic invested in Kecker & Van Nest and Knobbe
25 Martens in this case, just like Edwards invested in Paul

1 Weiss.

2 Instead, we have had outside reexam counsel work
3 on this from the public record alone.

4 THE COURT: Mr. Blumenfeld.

5 MR. BLUMENFELD: Your Honor, I don't know if you
6 want a response to that.

7 THE COURT: Go ahead. I have an inclination to
8 have further submissions. But go ahead.

9 MR. BLUMENFELD: Just to respond to that
10 briefly, further submissions would be fine with us, but this
11 really isn't about what's in the recesses of Mr. Nathan or
12 Ms. Nyarady's or anyone else's mind. What this reexam is
13 about is prior art, statements made at trial, and
14 patentability of our patents. It just doesn't seem to us
15 that there is any risk of inadvertent disclosure.

16 Having said that, if Your Honor would like us to
17 address further issues, we would be glad to do that.

18 THE COURT: I might be interested in taking a
19 look at some of the Federal Circuit -- I will mess up the
20 pronunciation -- but that, too, can and should be cited in
21 any submission.

22 But there was some other authority, I forget
23 which side.

24 MR. BLUMENFELD: I cited two opinions, one from
25 Judge Robinson, one from Judge Thyng, which we also would

1 be glad to provide.

2 THE COURT: Counsel, how many -- I am thinking
3 of just a brief letter, some short letter briefs. How many
4 pages do you think?

5 MR. BLUMENFELD: I wouldn't think we need more
6 than two or three pages.

7 THE COURT: I should think that would be
8 adequate. Mr. Ferrall, do you agree?

9 MR. FERRALL: I think that would be fine, Your
10 Honor.

11 THE COURT: We will set the limit at three. Let
12 me get an opening, an answer, and a reply. So we will have,
13 Mr. Blumenfeld, you open, and then we will get an answer and
14 reply. You know, you can cite anything you want. I don't
15 know whether it would be helpful for me to have the
16 affidavit appended to the letter, Mr. Blumenfeld, at all.

17 MR. BLUMENFELD: We would be happy to provide
18 that or any other materials from the reexam.

19 THE COURT: I just don't want a ton of paper.

20 MR. BLUMENFELD: It might be helpful to us to
21 submit -- I don't think you need the exhibits, the 200 pages
22 of exhibits from the declaration. But there are also the
23 statements that Medtronic made in the request itself, which
24 might be helpful.

25 THE COURT: Okay. Hold on just a second,

1 counsel.

2 (Pause.)

3 THE COURT: Okay. Counsel, let's do that. Do
4 you want to propose -- you can talk offline and agree on a
5 schedule for these submissions.

6 MR. BLUMENFELD: That is fine, Your Honor. We
7 would obviously, under the circumstances, where the reexams
8 are moving along, like to have the schedule be short.

9 THE COURT: Yes. It should be. That's why I
10 mention only, you know, limited page letter briefs. And you
11 shouldn't anticipate any kind of lengthy writing from me.
12 It's going to be short and to the point.

13 But I just don't feel comfortable -- both of you
14 are arguing very well. It seems to me, as they say, not to
15 be a slam dunk.

16 But I have a side issue that both of you could
17 help a little with.

18 The result of the rejection of two claims in the
19 reexam on the jury's verdict. We are in the process of
20 handling your posttrials, rather far along in that process.

21 MR. BLUMENFELD: These are -- I should let Mr.
22 Nathan respond to that. But these are initial office
23 actions. There is nothing final that has happened. At
24 least that's my understanding.

25 THE COURT: Well, are we likely to see

1 amendments? I am just trying to understand the potential
2 impact on my limited resources over here. Go ahead.

3 MR. BLUMENFELD: I will leave that to Mr.
4 Nathan.

5 MR. NATHAN: Good morning, or good afternoon,
6 judge.

7 To answer your question about amendments, in the
8 '552 patent, which was the one that was tried to the jury,
9 there will not be any amendments. And with respect to where
10 the reexam is, Edwards has not been heard from in the
11 reexam. There was an initial un-final office action
12 rejecting Claim 1, which is the one that went to the jury on
13 Irsek and Strecker, which is the prior art which was dropped
14 the night before trial.

15 I don't want to go over what Mr. Blumenfeld said
16 about characterizations of what I said and what Dr. Buller
17 said. But there is one thing that is for sure: Dr. Buller
18 and myself said nothing about Irsek and Strecker during the
19 trial. The words were never mentioned. And they have
20 extrapolated other statements that Dr. Buller and I said to
21 apply to Strecker and Irsek.

22 And we feel that we ought to be in a position to
23 respond to that.

24 So the reexamination process, as you know, can
25 go on for quite some time, is only at the beginning.

1 Edwards has been heard from.

2 THE COURT: That's helpful.

3 MR. FERRALL: Your Honor, I did want to raise
4 that, to make the record clear, we did submit, I believe, a
5 motion for leave to supplement the record on posttrial
6 motions with reference to the office action rejection. I
7 won't, obviously, argue it now. I wanted to bring that to
8 your attention.

9 THE COURT: You really don't want me to react to
10 that, that additional submission.

11 We will take a look at it. But, in fact, I can
12 tell you that we have taken a look at it. And I am really
13 not feeling you out there, Mr. Ferrall, as they say. Do you
14 get my drift?

15 MR. FERRALL: I hear you, Your Honor.

16 THE COURT: All right. So, counsel, make
17 sure -- I know this is going to be electronically filed, but
18 you want to make sure it comes to my attention as soon as
19 the briefing is completed. You need to figure out how to do
20 something to make sure that happens. Okay?

21 MR. BLUMENFELD: We will do that, Your Honor.

22 MR. FERRALL: We will.

23 THE COURT: I don't want the proverbial crack
24 there, I don't want it to fall through that crack. It
25 likely won't, given where we are in working on your

1 posttrials. But just to be sure. All right?

2 (Counsel respond "Thank you.")

3 THE COURT: Thank you, counsel.

4 Conference concluded at 12:49 p.m.)

5 Reporter: Kevin Maurer

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